IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MELISSA M. ZIMMERMAN Plaintiff, vs. ABBOTT LABORATORIES, an Illinois Corporation; BASF AG, a Foreign Corporation, BASF CORPORATION, a Delaware Corporation, KNOLL PHARMACEUTICAL COMPANY, a New Jersey Corporation, GLAXOSMITHKLINE plc, a Foreign Corporation, and SMITHKLINE BEECHAM d/b/a/ GLAXOSMITHKLINE, a Pennsylvania Corporation, Defendants.	Case No. 2:02CV3398 Judge Legrome D. Davis

ANSWER OF ABBOTT LABORATORIES AND KNOLL PHARMACEUTICAL COMPANY TO PLAINTIFF'S COMPLAINT WITH AFFIRMATIVE DEFENSES

Defendants Abbott Laboratories and Knoll Pharmaceutical Company (hereinafter referred to collectively as the "Defendants"), severing themselves from all other defendants, answer the plaintiff's Complaint (hereinafter "Complaint") on file herein as follows:

I. INTRODUCTION

1. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 1 of the Complaint.

2. Defendants admit that Abbott Laboratories is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Defendants deny the remaining allegations of paragraph 2 of the Complaint.

3-4. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraphs 3 and 4 of the Complaint.

5. Defendants admit that Knoll Pharmaceutical Company ("Knoll") is a New Jersey corporation. Defendants admit that Abbott Laboratories acquired Knoll on March 2, 2001. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of this paragraph directed at other defendants. Defendants deny the remaining allegations of paragraph 5 of the Complaint.

6. Defendants admit that Knoll has manufactured, marketed, distributed, promoted and sold Meridia in interstate commerce. Defendants deny the remaining allegations of paragraph 6 of the Complaint.

7. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 7 of the Complaint.

8. Defendants admit that Glaxosmithkline entered into an agreement with Knoll to distribute, market and sell Meridia. Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 8 of the Complaint.

9. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 9 of the Complaint.

10. Defendants admit that Glaxosmithkline entered into an agreement with Knoll to distribute, market and sell Meridia. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of this paragraph directed at other defendants. Defendants deny the remaining allegations of paragraph 10 of the Complaint.

11. Defendants deny the allegations of paragraph 11 of the Complaint.

II. JURISDICTION

12. Defendants admit the allegations of paragraph 12 of the Complaint.

III. FACTUAL BACKGROUND

13. Defendants admit that, on August 7, 1995, Knoll submitted a new drug application to the FDA seeking permission to manufacture and market Meridia for the treatment of obesity in 5, 10 and 15 mg. strength capsules. Defendants deny the remaining allegations of paragraph 13 of the Complaint.

14. Defendants admit that Meridia contributes to a patient's weight loss by affecting appetite control centers in the brain. Defendants admit that Meridia is recommended for obese patients with an initial body mass index of at least 30, or a body mass index of 27 in the presence of other risk factors. Defendants admit that Meridia has been associated with the elevation of blood pressure in some patients. Defendants admit that Meridia acts as a serotonin reuptake inhibitor on the central nervous system. Defendants deny the remaining allegations of paragraph 14 of the Complaint.

15. Defendants admit that an FDA memorandum reviewing a July 25, 1996 meeting requested by Knoll states that FDA officials asked if statistics were performed concerning the mean percentage change in plasma lipids in healthy obese patients in placebo-controlled studies; that the FDA memorandum states that Knoll representatives answered that they had not performed those statistics; and that the FDA memorandum states that Knoll representatives said that favorable trends in lipid profiles and glycemic control have been observed and that, in their opinion, the FDA weight-loss criteria had been satisfied. Defendants deny that this is a complete description of the July 25, 1996 meeting. Based upon Defendants' investigation to date, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 15 of the Complaint. Defendants' investigation of the allegations continues.

16. Defendants admit that the FDA memorandum reviewing a July 25, 1996 meeting states that Knoll representatives stated that there was a mean increase of approximately 2 mm Hg in systolic and diastolic blood pressure in sibutramine-treated subjects; that the FDA memorandum states that this effect was the same in normotensives and in hypertensives and was the same whether the patients were at the low end of the normal range or at the high end of the normal range; and that the FDA memorandum states that, in hypertensives, this effect is the same whether patients are on or off the anti-hypertensive medications. Defendants deny that the FDA memorandum states or otherwise indicates that FDA personnel found a significant risk of cardiac arrhythmia, cerebrovascular accidents (strokes), thrombocytopenia, bleeding disorders, heart palpitations, increased systolic and diastolic blood pressure and tachycardia associated with the ingestion of Meridia. Defendants deny that this is a complete description of the July 25, 1996 meeting. Based upon Defendants' investigation to date, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 16 of the Complaint. Defendants' investigation of the allegations continues.

17. Defendants admit that the FDA memorandum reviewing a July 25, 1996 meeting states that FDA officials said that they were concerned that any changes in blood pressure and cholesterol may not be independent risk factors; that this FDA memorandum states that Knoll representatives explained that some hypertension findings were significant and some were not and that the findings were grouped together for the data presented at the meeting; that the FDA memorandum states that FDA officials said that it was difficult to come to a firm conclusion on the risk/benefit of sibutramine based on the models presented at the July 25, 1996 meeting; that the FDA memorandum states that FDA officials said that there is so much data in the NDA and the data conflicts, thereby making it difficult to understand at that time what the effect of

sibutramine was; and that the FDA memorandum states that FDA officials said that the positive changes in lipids reported among patients taking sibutramine were not a consistent finding. Defendants deny that this is a complete description of the July 25, 1996 meeting. Based upon Defendants' investigation to date, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 17 of the Complaint. Defendants' investigation of the allegations continues.

18. Defendants admit that the FDA memorandum reviewing a July 25, 1996 meeting states that FDA officials recommended that Knoll conduct further analysis of blood pressure; and that the FDA memorandum states that Knoll representatives agreed to perform further analysis. Defendants deny that this is a complete description of the July 25, 1996 meeting. Based upon Defendants' investigation to date, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 18 of the Complaint. Defendants' investigation of the allegations continues.

19. Defendants admit that the FDA memorandum reviewing an October 21, 1996 meeting states that FDA officials said that they felt as if they were analyzing the same data as Knoll, but reaching different conclusions; that the FDA memorandum states that FDA officials said that they had a need for validation of analysis and adequate review time; and that the FDA memorandum states that Knoll replied that further analysis may dictate the labeling such as a black box warning and that it was willing to work with the FDA. Defendants deny that this is a complete description of the October 21, 1996 meeting. Based upon Defendants' investigation to date, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 19 of the Complaint. Defendants' investigation of the allegations continues.

20. Defendants admit that one member of the FDA's review team who reviewed the original NDA wrote that "sibutramine has an unsatisfactory risk - benefit ratio, and therefore this Reviewer recommends non-approval of the original submission of NDA 20-632."

21. Defendants admit that representatives from Knoll met with the FDA's Endocrinologic and Metabolic Drugs Advisory Committee on September 26, 1996, to consider Knoll's original NDA for Meridia. Defendants admit that the Advisory Committee voted 5-to-4 "no" to the question: Do the benefits of sibutramine outweigh the risks? Defendants state that the FDA minutes of this meeting speak for themselves and deny the remaining allegations of paragraph 21 as to what the FDA minutes state to the extent that they are inconsistent with those minutes. Defendants deny the remaining allegations of paragraph 21 of the Complaint.

22. Defendants admit that, on November 22, 1997, the FDA approved the use of Meridia in the United States at doses of 5 mg., 10 mg., and 15 mg. in the management of obesity, including weight loss and maintenance of weight loss, in conjunction with a reduced caloric diet. Defendants deny the remaining allegations of paragraph 22 of the Complaint.

23. Defendants admit that Knoll's marketing has included direct-to-consumer advertisements, including television commercials and print ads, and included promotional literature to be placed in the offices of doctors and other healthcare providers. Defendants admit that they represented that Meridia is a safe and effective treatment for obesity when used in a manner consistent with its labeling. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations directed at other defendants. Defendants deny the remaining allegations of paragraph 23 of the Complaint.

24. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations directed at other defendants. Defendants deny the remaining allegations of paragraph 24 of the Complaint.

25. Defendants admit that an estimated 8.5 million people in over 70 countries have used sibutramine for the management of obesity. Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 25 of the Complaint.

26. Defendants track adverse reactions temporally coincident with sibutramine but lack sufficient knowledge or information to form a belief as to the truth of plaintiff's allegations of adverse reactions reported to the FDA. Defendants deny the remaining allegations of paragraph 26 of the Complaint.

27. Defendants admit that FDA investigators conducted a routine inspection of Defendants' plant in Abbott Park, Illinois in March 2002. Defendants admit that FDA investigators identified potential violations of FDA regulations in the reporting of adverse drug experience information. Defendants state that they have responded to the FDA's concerns and deny the remaining allegations of paragraph 27 of the Complaint.

28. Defendants admit that, following reports of two deaths in persons purportedly taking sibutramine, the Italian Health Ministry temporarily suspended the sale of weight-loss products containing sibutramine. Defendants track adverse reactions temporally coincident with sibutramine but lack sufficient knowledge or information to form a belief as to the truth of plaintiff's allegations of adverse reactions reported by the United Kingdom and France. Defendants deny the remaining allegations of paragraph 28 and specifically deny that sibutramine caused any of the reported deaths.

29. Defendants admit that sibutramine has been associated with the elevation of blood pressure and/or heart rate in some patients. Defendants deny the remaining allegations of paragraph 29 of the Complaint.

30. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 30 of the Complaint.

31-34. Defendants deny the allegations of paragraphs 31 through 34 of the Complaint.

35. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations directed at other defendants. Defendants deny the remaining allegations of paragraph 35 of the Complaint.

COUNT I
STRICT PRODUCT LIABILITY
(FAILURE TO WARN)

36. Defendants incorporate by reference their responses to the foregoing paragraphs of the Complaint as if set out here in full.

37. Defendants admit that Knoll manufactures Meridia. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of this paragraph directed at other defendants. Defendants deny the remaining allegations of paragraph 37 of the Complaint.

38-40. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of these paragraph directed at other defendants. Defendants deny the remaining allegations of paragraphs 38-40 of the Complaint.

COUNT II
STRICT PRODUCT LIABILITY
(DEFECTIVE DESIGN)

41. Defendants incorporate by reference their responses to the foregoing paragraphs of the Complaint as if set out here in full.

42. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of this paragraph directed at other defendants. Defendants deny the remaining allegations of paragraph 42 of the Complaint.

43. Defendants deny the allegations of paragraph 43 of the Complaint.

COUNT III
NEGLIGENCE

44. Defendants incorporate by reference their responses to the foregoing paragraphs of the Complaint as if set out here in full.

45. Defendants admit to all duties imposed by law. Defendants deny the remaining allegations of paragraph 45 of the Complaint.

46-50. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of these paragraphs directed at other defendants. Defendants deny the remaining allegations of paragraphs 46 through 50 of the Complaint.

COUNT IV
BREACH OF IMPLIED WARRANTY

51. Defendants incorporate by reference their responses to the foregoing paragraphs of the Complaint as if set out here in full.

52. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations directed at other defendants. Defendants deny the remaining allegations of paragraph 52 of the Complaint.

53. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 53 of the Complaint.

54-55. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of these paragraph directed at other defendants. Defendants deny the remaining allegations of paragraphs 54 and 55 of the Complaint.

In response to the unnumbered paragraph beginning "WHEREFORE, Plaintiff demands compensatory damages against Defendants…," Defendants deny that plaintiff is entitled to any relief whatsoever.

Defendants further deny each and every allegation of the Complaint not expressly admitted.

AFFIRMATIVE DEFENSES

First Defense

The Complaint fails to state a claim upon which relief may be granted.

Second Defense

The subject products and conduct of Defendants at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations and policies in violation of the Supremacy Clause of the United States Constitution.

Third Defense

To the extent plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Fourth Defense

Plaintiff's claims are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the approval and withdrawal of approval of

prescription drugs and the content of warnings and labeling for prescription drugs. The remedies sought by the plaintiff with regard to advertising, warnings or labeling are subject to the exclusive regulation of the FDA and this court should, therefore, abstain from adjudicating plaintiff's claims relating to warnings and labeling in deference to the FDA.

Fifth Defense

Plaintiff's claims are barred, in whole or in part, because plaintiff has not sustained present physical injuries or injuries to property necessary to recover under a claim for strict liability or negligence.

Sixth Defense

Plaintiff's claims are barred, in whole or in part, because plaintiff has not sustained injuries or damages as a result of the matters alleged in the Complaint.

Seventh Defense

The alleged injuries and damages to plaintiff were not proximately caused by any acts or omissions of the Defendants.

Eighth Defense

Plaintiff's alleged injuries and damages were the result of pre-existing conditions which were unrelated to any conduct of, or product placed in the stream of commerce by, Defendants.

Ninth Defense

Plaintiff's alleged injuries and damages were the result of an idiosyncratic reaction, pre-existing medical condition and/or occurred by operation of nature which Defendants could not reasonably foresee and as a result of circumstances over which Defendants had, and continue to have, no control.

Tenth Defense

The alleged injuries and damages to plaintiff were proximately caused by the superseding and intervening acts of third parties other than Defendants.

Eleventh Defense

The alleged injuries to plaintiff were directly and proximately caused and contributed to in whole or in part by actions of persons, third-parties, or agents other than Defendants, over whom Defendants have no direction, control or authority. Therefore, plaintiff's recovery, if any, should be apportioned by common law and statute.

Twelfth Defense

The alleged injuries to plaintiff were proximately caused by the misuse, abuse, alteration and/or failure properly to utilize, maintain or care for Defendants' products by persons other than Defendants.

Thirteenth Defense

The alleged injuries to plaintiff were caused by the plaintiff's assumption of risk or contributory negligence. Plaintiff's damages, if any, must therefore be reduced proportionately or altogether barred pursuant to applicable law.

Fourteenth Defense

The alleged injuries to plaintiff were directly and proximately caused and contributed to by the actions of other persons, who caused changes and alterations to be made to the Defendants' products and said changes and alterations proximately caused or contributed to the injuries alleged by plaintiff, and avoided any and all alleged warranties, express and/or implied.

Fifteenth Defense

Plaintiff's product liability causes of action are barred because the benefits of the product outweighed its risks.

Sixteenth Defense

Plaintiff's claims are barred in whole or in part by their failure to assert a safer alternative design for the product at issue.

Seventeenth Defense

At the time that the Defendants' product was distributed, there was no practical or technically feasible alternative design that would have prevented harm without substantially impairing or compromising the reasonably anticipated or intended function of the Defendants' product or the product's usefulness or desirability which is recognized by the ordinary person with the ordinary knowledge common to the community.

Eighteenth Defense

Adequate and complete warnings and instructions were provided with Defendants' product and the Defendants' product was neither defective nor unreasonably dangerous when used according to label instructions.

Nineteenth Defense

If any alleged injury was caused by Defendants' product, the injury was caused by an unavoidably unsafe aspect of the Defendants' product and the Defendants' product was accompanied by an adequate warning or instruction.

Twentieth Defense

Defendants provided adequate and complete warnings with the product in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

Twenty-first Defense

Defendants plead the learned intermediary doctrine under which a prescription drug manufacturer is only under a duty to warn the learned intermediary – the physician – and not the

ultimate user of any risks related to the prescription drug. Accordingly, Defendants did not breach any duty to warn the plaintiff, and the Meridia which may have been used in this case was neither unreasonably dangerous nor defective by virtue of any alleged absence of warning to the plaintiff.

Twenty-second Defense

Defendants' product, which plaintiff alleges in the Complaint to be defective, is a medical and pharmaceutical product which met standards of the state of the art and the state of medical and scientific knowledge at the time of its manufacture to the extent of the knowledge then available to the medical community.

Twenty-third Defense

There is no claim of negligence per se for violations of the Federal Food, Drug and Cosmetics Act or of the related FDA regulations under governing law because there is no expression of legislative intent that the statute become a basis for the imposition of civil liability.

Twenty-fourth Defense

Plaintiff's claims for breach of implied warranty are barred because plaintiff has sought a remedy in tort.

Twenty-fifth Defense

Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which Defendants specifically deny, then plaintiff failed to give timely notice of any breach thereof.

Twenty-sixth Defense

Plaintiff's claims for breach of implied warranty are barred by reasons of the absence of privity of contract between the plaintiff and Defendants.

Twenty-seventh Defense

Any express or implied warranties alleged to have been made by Defendants were disclaimed.

Twenty-eighth Defense

Defendants deny, to the extent the action alleged may have occurred, that any entity engaging in activities alleged was acting as the agent or servant of Defendants, or at the instruction or subject to the control of Defendants with regard to any acts or omissions of such third parties as a matter of law.

Twenty-ninth Defense

To the extent plaintiff's alleged injuries occurred and/or causes of action arose prior to the applicable statutory period, plaintiff's claims are barred by the statute of limitations and repose.

Thirtieth Defense

Defendants aver that they did not participate in, authorize, ratify, or benefit from the alleged wrongful acts that are asserted in the Complaint.

Thirty-first Defense

The plaintiff did not purchase Meridia from any of the Defendants, and the plaintiff never received or relied upon any representation allegedly made by any of the Defendants.

Thirty-second Defense

Plaintiff's claims are barred or reduced by plaintiff's failure to mitigate damages.

Thirty-third Defense

Plaintiff's claims are barred or reduced by the doctrine of avoidable consequences.

Thirty-fourth Defense

Plaintiff's claims are barred in whole or in part under the Restatement (Third) of Torts: Products Liability Sections 2, 4 and 6 *et seq.*, and comments thereto.

Thirty-fifth Defense

Plaintiff's claims are barred in whole or in part under the Restatement (Second) of Torts Section 402A *et seq.*, and comments thereto.

Thirty-sixth Defense

Plaintiff's claims are barred, reduced and/or limited pursuant to all applicable statutory and common law regarding limitations of awards, caps on recovery, set-offs, and medical or other payments from collateral sources.

Thirty-seventh Defense

Plaintiff's claims are barred in whole or in part by the doctrines of laches, waiver and estoppel.

Thirty-eighth Defense

Defendants deny that they have been guilty of any conduct which warrants the issue of punitive damages being submitted to a jury.

Thirty-ninth Defense

Consideration of any punitive damages in this civil action would violate the Due Process clauses of the United States Constitution by allowing standardless discretion to the jury to determine punishment and by depriving Defendants of prior notice of the consequences of its alleged acts.

Fortieth Defense

Plaintiff has failed to join indispensable parties necessary for the just adjudication of this matter.

Forty-first Defense

Plaintiff's alleged claims and rights against Defendants, if any, are barred in whole or in part by public policy considerations.

Forty-second Defense

Any recovery by the plaintiff must be reduced or offset by amounts the plaintiff has received or will receive from others for the same injuries claimed in this lawsuit.

Forty-third Defense

To the extent that the plaintiff has sustained personal injuries, plaintiff's claim for pre-judgment interest is not recoverable under governing law.

Forty-fourth Defense

Plaintiff's claims for injunctive and equitable relief are barred because there is an adequate remedy at law and because the plaintiff faces no threat of future irreparable injury.

Forty-fifth Defense

Defendants incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions *BMW of North America v. Gore*, 517 U.S. 559 (1996) and *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), together with all such standards applicable under state law.

Forty-sixth Defense

Defendants hereby give notice that they intend to rely upon such other defenses as may become available or appear during the course of discovery proceedings in this case and hereby reserve the right to amend this Answer to assert such defenses.

WHEREFORE, Defendants pray for judgment in their favor and against the plaintiff dismissing the plaintiff's Complaint with prejudice, for costs of courts, and for such other and further relief as may be appropriate.

Dated: October 21, 2002

Respectfully submitted,

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BY:_____
Joseph E. O'Neil, Esq.
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ATTORNEYS FOR DEFENDANTS, ABBOTT LABORATORIES AND KNOLL PHARMACEUTICAL COMPANY

CERTIFICATE OF SERVICE

I, Sheri C. Crawford, an attorney, hereby certify that a true and correct copy of the foregoing Answer of Abbott Laboratories and Knoll Pharmaceutical Company to Plaintiff's Second Amended Class Action Complaint was served via US Postal Service 1st Class Mail Service on the following persons on the 21st day of October, 2002.

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